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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,325	02/16/2006	Shailesh Bhamare	SMC-PT004	2977

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,325	BHAMARE ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 6, 8 - 11, 13, 14, 16 ,17, 19 - 26, 28, 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 6, 8 - 11, 13, 14, 16 ,17, 19 - 26, 28, 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2008 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 – 3, 5, 6, 9, 16, 17 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30, 37, 39 and 40 of copending Application No. 10/495961. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 6, 2008 and those set forth below.

Applicant notes that there are additional rejections in both cases and once all of the set rejections have been obviated in one case, applicants will consider the filing of a terminal disclaimer.

As the merits of this rejection have not been argued and a terminal disclaimer has not been filed, the rejection is maintained.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22 – 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims of the instant application require a C_{max} with 80 – 120% of a single does of an immediate release formulation (claims 22 and 23) or T > MIC of a certain concentration for a certain amount of the dosing interval (claims 24 and 25). On p 16 - 18 of the instant specification, the formulation of example 2, which comprises 5.0% carbomer 971P and 15.0% carbomer 974P, is administered to subjects. Only one other formulation with different weight percentages of the two carbomers (example 3, p 12) is prepared but pharmacokinetic data is not reported for this formulation, or the other formulations which also comprise 5.0% carbomer 971P and 15.0% carbomer 974P but contain different weight percentages of the excipients Pharmatose DCL21 and magnesium stearate. The amounts of active ingredient,

controlled release materials and other excipients present in the specification can alter the release profile of the drug and the maximal concentration of the drug (C_{max}) of the formulation when administered. Therefore, the specification provides insufficient written description for all composition(s) which are capable of providing the claimed pharmacokinetic parameters as claimed in the instant application. Applicant has not provided an adequate written description of species that meet the functional limitations to support the full genus of compositions with the claimed physical properties encompassed by the instant claims.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6 and 8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of the use of the terms "carbomer 971P" and "carbomer 974P". Applicant has submitted information showing that "carbomer 971P" and "carbomer 974P" are generic terms and the numbers indicates the grades used by a variety of suppliers. These arguments are found persuasive so this argument is WITHDRAWN.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 6, 8 – 11, 13, 14, 16, 17, 19 – 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kshirsagar et al. (WO 04/019901). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 6, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Kshirsagar fails to discloses the carbomer concentration range of about 5% to about 50% by weight, as Kshirsagar's disclosure teaches using 1% to 35% by weight. Each example discloses a composition containing a percentage of carbomer below the claimed range or none at all. None of the examples disclose "at least two carbomers" as each instant claim requires. Drug release is greatly accelerated when a lower percentage mixture of carbomers is used, providing an advantage to the Applicant's claimed composition. The advantage of using two or more carbomers is evidenced by the examples of Applicant which show a minimum of 5 hours, up to 10 or more hours elapsed prior to at least 80% of the drug being released, whereas the compositions of Kshirsagar show at least 80% drug release in less than 4 hours. Kshirsagar teaches the use of carbomers as integrity enhancers, not as sustained release components, so a person of ordinary skill in the art would therefore have no motivation to modify the percentage of carbomer in Kshirsagar's composition to improve the sustained release properties.

These arguments are not found to be persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the length of time to achieve 80% release of the drug) are not recited in the rejected claim(s). Although the claims

are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). C_{max} and T > MIC parameters are recited in claims 22 – 25. C_{max} is a time independent pharmacokinetic parameter and the levels of T > MIC are percentages of the dosing interval and therefore the limitations do not require the same absolute dosing interval.

The teachings of a prior art document are not limited to the examples but are prior art for all that they disclose. While no examples prepared by Kshirsagar et al. use a combination of carbomers, as previously cited, Kshirsagar et al. dose contemplate combinations of CARBOPOL® 971P and CARBOPOL® 974P (p 16, ln 25 – 28).

The function of a particular ingredient in a composition cannot be separated from its function and an ingredient can serve multiple purposes in a composition, all of which may not and need not be appreciated by the prior art. Both the cited prior art and the instant claims have compositions comprising at least two carbomers. The range for the carbomer concentration of 1% to 35% of Kshirsagar et al. overlaps with the range of about 5% to about 50% by weight claimed by applicant. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) **MPEP 2144.05**

12. Claims 1 – 3, 6, 8, 9 – 11, 13, 14, 19, 21, 22, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odidi et al. (WO 02/056861).

Odidi et al. discloses syntactic foams suitable as carriers for pharmaceutical (abstract) such as the cephalosporin cefprozil (p 21, ln 19). In example 3 (p 24, ln 17 – 25), showing a methodology for preparing the syntactic foam, a composition comprising 16% by weight carbomer 971P, 11% by weight carbomer 974P (total carbomer weight 27%) and 55% by weight of cellulose microspheres is prepared. Lactose or microcrystalline cellulose microspheres can also be used in the syntactic foam (p 11, ln 1 – 5). The formed foam, comprising active ingredient, microsphere and carbomer, can be compressed in a shaped composite, such as a tablet (p 21, ln 1 – 3).

Odidi et al. does not explicitly prepare a composition comprising a cephalosporin antibiotic and at least two carbomers.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a syntactic foam with cefprozil as the active ingredient as such compositions are disclosed by Odidi et al. One of ordinary skill would be motivated to prepare such a form in order to prepare a cefprozil containing dosage form to use in the treatment of bacterial infections and would reasonable expect success as Odidi et al. discloses that syntactic foam compositions are suitable for the delivery of pharmaceuticals such as cefprozil. Lactose or microcrystalline cellulose microspheres are taught as functionally equivalent microsphere materials that are suitable for use in the preparation of these foams. One of ordinary skill would select the particular ingredients and amount of microspheres based the cost and availability of the various materials and the specific demands (such as ingredient interactions or potential allergies of the intended patient population).

Odidi et al. teaches composition comprising cefprozil, which reads on cephalosporin antibiotic, and at least two carbomers at a concentration ranging from 5% to 50% by weight of the composition. Claims 22 and 24 recite a composition comprising a cephalosporin antibiotic, and at least two carbomers at a concentration ranging from 5% to 50% by weight of the composition. As the compositions of Odidi et al. and those prepared and claimed by Applicant as both comprisws a cephalosporin antibiotic and at least two carbomers at a concentration ranging from 5% to 50% by weight of the composition, the compositions of Odidi et al. will necessarily have a C_{max} with 80 – 120% of a single dose of an immediate release formulation and a T > MIC at 0.25 mcg/ml is achieved for 75% of the dosing interval and a T > MIC of 2 mcg/ml is achieved for almost 49% of the dosing interval. Compositions with the same ingredients must necessarily have the same properties.

13. Claims 1 – 6, 8, 9 – 11, 13, 14, 19, 21, 22, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Odidi et al. as applied to claims 1 – 3, 6, 8, 9 – 11, 13, 14, 19, 21, 22, 28 and 29 and further in view of Vermeulen et al. (US 5872104).

Odidi et al. discloses syntactic foam compositions comprising active ingredient such a cefprozil, carbomer 971P, carbomer 974P and microspheres, which can be made from cellulose, lactose or microcrystalline cellulose.

Odidi et al. does not disclose the dosage of the cefprozil.

Vermeulen et al. discloses the usual oral dosage of cefprozil is 250 mg every 12 hours (col 25, ln 47).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the composition comprising cefprozil, at least two carbomers as taught by Odidi et al. and to use the 250 mg dosage as taught by Vermeulen et al. as the usual oral dosage for cefprozil.

14. Claims 1 – 6, 8, 9, 13, 14, 16, 17, 19 – 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzenhelder (US 6,399,086) in view of Mayron (US 3,074,852). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 6, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that neither reference teaches a composition comprising a mixture of at least two carbomers at a concentration of 5% to 50% by weight. Example 2 of Mayron comprising a total of 89% by weight carbomers, well outside the range of about 5% to about 50% claimed by Applicant. Katzenhelder fails to remedy this deficiency as it does not disclose the use of carbomers at all.

These arguments are not found to be persuasive. While example 2 of Mayron does contain a total amount of carbomers which is outside the range of the instant claims, example 5 of Mayron discloses a composition with a much higher percentage of active ingredient (46%) and 46% by weight carbomer. Depending on the amount of drug and other ingredients present in the unit dose, one of ordinary skill would optimize the amount of carbomers present in the composition, arriving at the composition of the

instant claims. The amount of a specific ingredient in a composition is a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success.

15. Claims 1 – 6, 8 – 11, 13, 14, 16, 17, 19 – 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzenhelder and Mayron as applied to claims 1 – 6, 8, 9, 13, 14, 16, 17, 19 – 26, 28 and 29 above, and further in view of Patel (US 6,248,363). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 6, 2008 and those set forth below.

Applicants traverse this rejection on the grounds that Patel fails to teach a composition comprising at least two carbomers and therefore fails to remedy the deficiencies of Katzenhelder and Mayron.

This is not found persuasive as the use of at least carbomers is disclosed by the cited prior art, as discussed in more detail above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Jake M. Vu/
Primary Examiner, Art Unit 1618